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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,736	02/24/2000	Mich B. Hein	TSRI-184.2con4	5292

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	8

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/512,736	HEIN ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2000 and 10 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-66* is/are pending in the application.

4a) Of the above claim(s) *21-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 53-66, in Paper No. 7 is acknowledged. No grounds for traversal are stated.

2. The requirement is still deemed proper and is therefore made FINAL.

Priority

3. A foreign priority is not claimed.

Information Disclosure Statement

4. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, is attached to the instant Office action.

Drawings

5. The drawings are objected to by the Draftsperson as informal for the reasons indicated on Form PTO 948.

Specification

6. The continuing data does not agree with the face of the file.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 53-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. The claims are drawn to plant cells containing nucleotide sequences encoding an immunoglobulin product containing at least a portion of an immunoglobulin light chain and the immunoglobulin product encoded by said sequences. The claims are also drawn to plant cells wherein the immunoglobulin product is a single-chain antigen binding protein, one-half an immunoglobulin molecule, an immunoglobulin light chain, an abzyme, an Fab, an Fab', an f(ab')2, an Fv, an antibody, and wherein the immunoglobulin product includes a J chain.

10. However, the specification does not set forth what specific structural or physical features define the claimed plant cells. The specification only discloses plant cells comprising nucleotide sequences encoding an immunoglobulin product that is the catalytic monoclonal antibody 6D4 (pages 52-86 *Examples 1-13*), and plant cells comprising nucleotide sequences encoding the heavy and light chains of the murine antibody Guy's 13, a murine J-chain, and a rabbit SC (pages 90-102 *Example 15*). The identities of the claimed plant cells are uncertain. One skilled in the art could not predict the structure and function of plant cells comprising nucleotide sequences encoding unspecified immunoglobulin products. The structural and physical features of the claimed plant cells cannot be ascertained in the absence of information about the specific functional activities of the nucleotide sequences they comprise.

11. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it

thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

12. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed plant cells, one skilled in the art would not have been in possession of the claimed plant cells at the time this application was filed.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The transitional phrase "containing" renders claim 53 indefinite because the scope of nucleotide sequences and immunoglobulin products encompassed by the claims is unclear.

15. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "one-half an immunoglobulin molecule" renders claim 55 indefinite because it is unclear in what way the immunoglobulin molecule would be divided to produce the one-half.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 53-56 and 58-63 are rejected under 35 U.S.C. 102(b) as being anticipated by During (Dissertation, University of Koln, FRG, July 9, 1988, Applicant's IDS #5).

18. The claims are drawn to dicotyledonous plant cells containing nucleotide sequences encoding an immunoglobulin product containing at least a portion of an immunoglobulin light chain and the immunoglobulin product encoded by said sequences. The claims are also drawn to dicotyledonous plant cells wherein the immunoglobulin product is a single-chain antigen binding protein, one-half an immunoglobulin molecule, an immunoglobulin light chain, an Fab, an Fab', an f(ab')2, an Fv, an antibody, and a J-chain.

19. During teaches transgenic tobacco cells which contain and express nucleotide sequences encoding immunoglobulin heavy and light chains of an anti-NP-IgM antibody (page 23, page 89, page 112). An antibody inherently comprises at least a portion of an immunoglobulin light chain, a single-chain antigen binding protein, one-half an immunoglobulin molecule, an immunoglobulin light chain, an Fab, an Fab', an f(ab')2, an Fv, and a J chain.

20. Accordingly, Claims 53-56 and 58-63 are anticipated by During.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 53-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over During (Dissertation, University of Koln, FRG, July 9, 1988, Applicant's IDS #5) in view of Applicant's admitted prior art.

23. The teachings of During are discussed *supra*.

24. During does not teach an immunoglobulin product that is an abzyme, or transgenic monocotyledonous or algal plant cells.

25. Applicant discloses that abzymes and methods for transforming a wide range of plant cells, including monocotyledonous or algal plant cells, were known in the art at the time of Applicant's invention (the 6D4 abzyme of Tramontano et al. cited on page 52 lines 19-20, and the numerous plant transformation references cited on pages 19-22).

26. Given the success of During in making transgenic tobacco cells which contain and express nucleotide sequences encoding immunoglobulin heavy and light chains of an anti-NP-IgM antibody, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to also use an abzyme or a method of transforming a monocotyledonous or algal plant cell as taught by the prior art, for the purpose of producing a transgenic plant comprising an immunoglobulin product, without any surprising or unexpected results.

27. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Double Patenting

28. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

29. Claims 53-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-12 of U.S. Patent No. 5,959,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transgenic plant comprising nucleotide sequences encoding immunoglobulin heavy- and light-chain polypeptides of U.S. Patent No. 5,959,177 would encompass the plants cells containing nucleotide sequences encoding the immunoglobulin products of claims 53-66 of the instant application. Accordingly, claims 53-66 are rendered obvious by claims 6-12 of U.S. Patent No. 5,959,177.

30. Claims 53-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,639,947. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transgenic plants comprising nucleotide sequences encoding immunoglobulin heavy- and light-chain polypeptides of U.S. Patent No. 5,639,947 would encompass the plants cells containing nucleotide sequences encoding the immunoglobulin products of claims 53-66 of the instant application. Accordingly, claims 53-66 are rendered obvious by claims 1-7 of U.S. Patent No. 5,639,947.

31. Claims 53-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,202,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because

the plant cell composition comprising an immunologically active glycosylated immunoglobulin molecule of claims 1-3 of U.S. Patent No. 5,202,422 would encompass the plants cells containing nucleotide sequences encoding the immunoglobulin products of claims 53-66 of the instant application. Accordingly, claims 53-66 are rendered obvious by claims 1-3 of U.S. Patent No. 5,202,422.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
November 16, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600